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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/277,401	03/26/99	JAYE M	22944-USA

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EXAMINER	
TUNG, P	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/277,401	Applicant(s) Jaye et al.
	Examiner Peter Tung	Group Art Unit 1652

☒ Responsive to communication(s) filed on *Feb 12, 2001* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *7, 8, 10, 11, 13-16, 19-25, 28-32, 34, 35, 37, 39-41, 43-47, 49-53* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *7, 8, 10, 11, 13-16, 19-25, 28-32, 34, 35, 37, 39-41,* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group IX, claim 20 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that 35 U.S.C. 121 requires that the involved inventions which are distinct from each other be also independent from each other. Applicants argue that the classification of the subject matter is incorrect and that claims 46 and 52 involve a LIPG polypeptide, a proper search of the involved claims can be conducted without serious burden.

This is not found persuasive because interpretation of 35 U.S.C 121 requires that the involved inventions be either distinct *or* independent (MPEP 803). Undue burden is required as claims 46 and 52 are drawn to methods of using an LIPG polypeptide and would require a search of non-patent literature not required for the search of Group IX. The classification of the subject matter would not have any bearing on searching non-patent literature.

The requirement is still deemed proper and is therefore made FINAL.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 7, drawn to anti-LIPG antibody, classified in class 530, subclass 387.1.

II. Claim 8, drawn to DNA encoding anti-LIPG antibody, classified in class 536, subclass 23.5.

III. Claim 10, drawn to intracellular binding protein, classified in class 530, subclass 350.

IV. Claim 11, drawn to DNA encoding intracellular binding protein, classified in class 536, subclass 23.5.

V. Claim 13, drawn to LIPG enzymatic activity inhibitor, classified in class 435, subclass 198.

VI. Claims 14-16, drawn to a ribozyme LIPG expression inhibitor, classified in class 536, subclass 24.5.

VII. Claim 19, drawn to DNA encoding an LIPG polypeptide, classified in class 435, subclass 198.

VIII. Claim 20, 66-71, 72 and 77-84 drawn to human LIPG polypeptide, classified in class 435, subclass 198.

IX. Claim 20, 66-71, 73 and 77-84 drawn to rabbit LIPG polypeptide, classified in class 435, subclass 198.

X. Claim 20, 66-71, 74 and 77-84 drawn to LIPG polypeptide of SEQ ID NO: 6, classified in class 435, subclass 198.

XI Claim 20, 66-71, 75 and 77-84 drawn to LIPG polypeptide of SEQ ID NO: 8, classified in class 435, subclass 198.

XII Claim 20, 66-71, 74 and 77-84 drawn to LIPG polypeptide of SEQ ID NO: 10, classified in class 435, subclass 198.

XIII. Claims 21 and 22, drawn to LIPG expression enhancer, classified in class 530, subclass 350.

XIV. Claims 23-25, 29, 30, 32, 34, 35, 39 and 43, drawn to a method for raising HDL by lowering the level of LIPG, classified in class 514, subclass 44.

XV. Claims 28 and 40, drawn to a method for raising HDL by administering anti-LIPG antibody, classified in class 424, subclass 130.1.

XVI. Claims 31 and 37, drawn to a method for raising HDL by administering a ribozyme which cleaves mRNA encoding LIPG, classified in class 514, subclass 44.

XVII. Claim 41, drawn to a method for raising HDL by administering DNA encoding intracellular binding protein, classified in class 514, subclass 44.

XVIII. Claim 44, drawn to a method for raising HDL by administering apolipoprotein AI, classified in class 514, subclass 2.

XIX. Claims 45-47, drawn to a method for lowering VLDL by increasing LIPG activity, classified in class 424, subclass 94.1.

XX. Claims 45 and 49, drawn to a method for lowering VLDL by administering an LIPG activity enhancer, classified in class 514, subclass 2.

XXI. Claims 45 and 50, drawn to a method for lowering VLDL by administering an LIPG expression enhancer, classified in class 514, subclass 44.

XXII. Claims 51 and 52, drawn to a method for lowering LDL by increasing LIPG enzymatic activity, classified in class 514 , subclass 2.

XXIII. Claims 51, 53, 55 and 56, drawn to drawn to a method for lowering LDL by administering an LIPG expression vector, classified in class 514, subclass 44.

XXIV. Claim 57, drawn to a method for lowering LDL by administering an enhancer of enzymatic reactions, classified in class 514, subclass 2.

XXV. Claim 58, drawn to a method for lowering VLDL by administering an enhancer of enzymatic reactions, classified in class 514, subclass 2.

XXVI. Claim 59, drawn to a method comprising measuring LIPG polypeptide levels, classified in class 435, subclass 19.

XXVII. Claim 63, drawn to a method for determining LIPG-HDL-apoAI enzymatic reaction inhibitors, classified in class 435, subclass 4.

XXVIII. Claim 64, drawn to a method for determining LIPG-VLDL enzymatic reaction enhancers, classified in class 435, subclass 4.

XXIX. Claim 65, drawn to a method for determining LIPG-LDL enzymatic reaction enhancers, classified in class 435, subclass 4.

3. The inventions are distinct, each from the other because of the following reasons:

Each of Groups I-XIII is directed to a separate and distinct invention. Group I is directed toward anti-LIPG antibody, Group II is directed toward DNA encoding anti-LIPG antibody, Group III is directed toward intracellular binding protein, Group IV is directed toward DNA encoding intracellular binding protein, Group V is directed toward LIPG enzymatic activity inhibitor, Group VI is directed toward ribozyme LIPG expression inhibitor, Group VII is directed toward DNA

encoding an LIPG polypeptide, Group VIII is directed toward human LIPG polypeptide, Group IX is directed toward rabbit LIPG polypeptide, Group X is directed toward LIPG polypeptide of SEQ ID NO: 6, Group XI is directed toward LIPG polypeptide of SEQ ID NO: 8, Group XII is directed toward LIPG polypeptide of SEQ ID NO: 10 and Group XIII is directed toward an LIPG expression enhancer.

4. The products of Groups I-XIII would be expected to have distinct morphological, functional, chemical and physical properties as indicated by their divergent classification, process of making and process of using. These products are capable of separate manufacture, use, or sale as claimed, and are patentably distinct.

5. It is noted that for Groups VIII-XII, claims drawn to human LIPG, rabbit LIPG and LIPG of SEQ ID NOS:6, 8 and 10 will be rejoinded depending upon the source of the specific proteins, e.g., if SEQ ID NO:6 is human LIPG, Groups VIII and X will be rejoined. No two sequences will be rejoined in a Group even if the sequences are of the same species, unless one of the sequences is a subsequence of the other.

6. Each of Groups XIV-XXIX is directed to a separate and distinct invention. Group XIV is directed to a method of raising HDL by lowering the level of LIPG, Group XV is directed to a method of raising HDL by administering anti-LIPG antibody, Group XVI is directed to a method of raising HDL by administering a ribozyme which cleaves mRNA encoding LIPG, Group XVII is directed to a method of raising HDL by administering DNA encoding intracellular binding protein, Group XVIII is directed to a method of raising HDL by administering apolipoprotein AI, Group

XIX is directed to a method of lowering VLDL by increasing LIPG activity, Group XX is directed to a method of lowering VLDL by administering an LIPG activity enhancer, Group XXI is directed to a method of lowering VLDL by administering an LIPG expression enhancer, Group XXII is directed to a method of lowering LDL by increasing LIPG enzymatic activity, Group XXIII is directed to a method of lowering LDL by administering an LIPG expression vector, Group XXIV is directed to a method of lowering LDL by administering an enhancer of enzymatic reactions, Group XXV is directed to a method of lowering VLDL by administering an enhancer of enzymatic reactions, Group XXVI is directed to a method comprising measuring LIPG polypeptide levels, Group XXVII is directed to a method of determining LIPG-HDL-apoAI enzymatic reaction inhibitors, Group XXVIII is directed to a method of determining LIPG-VLDL enzymatic reaction enhancers and Group XXIX is directed to a method of determining LIPG-LDL enzymatic reaction enhancers. These methods are distinct both physically and functionally, require different process steps, reagents and parameters and produce different products.

7. Inventions of Group I and Group XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as using the anti-LIPG antibody to detect the presence of LIPG polypeptide.

8. Inventions of Group IV and Group XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in using the DNA to heterologously express intracellular binding protein.

9. Inventions of Group VI and Group XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in an assay for LIPG mRNA.

10. Inventions of Groups VIII-XII and Group XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in the production of anti-LIPG antibodies.

11. Inventions of Group XIII and Group XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in the production of anti-LIPG expression enhancer antibodies.

12. Inventions of Group VII and Group XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in the heterologous production of LIPG polypeptide.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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